

tions 350g to 350l-1, 379j-31, 384a to 384d, 399c, and 399d of this title, section 7625 of Title 7, Agriculture, and section 280g-16 of Title 42, The Public Health and Welfare, amended sections 331, 333, 334, 350b to 350d, 350f, 374, 381, 393, and 399 of this title and section 247b-20 of Title 42, and enacted provisions set out as notes under sections 331, 334, 342, 350b, 350d, 350e, 350g to 350j, 350l, and 381 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 2201 of this title and Tables.

AMENDMENTS

2011—Pub. L. 111-353 amended section generally. Prior to amendment, section related to grants to States for inspections.

2009—Subsec. (b). Pub. L. 111-31, §103(n), made technical amendment to reference in original act which appears in text as reference to section 398 of this title.

CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendment by Pub. L. 111-353 to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

§ 399a. Office of the Chief Scientist

(a) Establishment; appointment

The Secretary shall establish within the Office of the Commissioner an office to be known as the Office of the Chief Scientist. The Secretary shall appoint a Chief Scientist to lead such Office.

(b) Duties of the Office

The Office of the Chief Scientist shall—

(1) oversee, coordinate, and ensure quality and regulatory focus of the intramural research programs of the Food and Drug Administration;

(2) track and, to the extent necessary, coordinate intramural research awards made by each center of the Administration or science-based office within the Office of the Commissioner, and ensure that there is no duplication of research efforts supported by the Reagan-Udall Foundation for the Food and Drug Administration;

(3) develop and advocate for a budget to support intramural research;

(4) develop a peer review process by which intramural research can be evaluated;

(5) identify and solicit intramural research proposals from across the Food and Drug Administration through an advisory board composed of employees of the Administration that shall include—

(A) representatives of each of the centers and the science-based offices within the Office of the Commissioner; and

(B) experts on trial design, epidemiology, demographics, pharmacovigilance, basic science, and public health; and

(6) develop postmarket safety performance measures that are as measurable and rigorous as the ones already developed for premarket review.

(June 25, 1938, ch. 675, §1010, formerly §910, as added Pub. L. 110-85, title VI, §602, Sept. 27, 2007, 121 Stat. 898; renumbered §1010, Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

§ 399b. Office of Women's Health

(a) Establishment

There is established within the Office of the Commissioner, an office to be known as the Office of Women's Health (referred to in this section as the "Office"). The Office shall be headed by a director who shall be appointed by the Commissioner of Food and Drugs.

(b) Purpose

The Director of the Office shall—

(1) report to the Commissioner of Food and Drugs on current Food and Drug Administration (referred to in this section as the "Administration") levels of activity regarding women's participation in clinical trials and the analysis of data by sex in the testing of drugs, medical devices, and biological products across, where appropriate, age, biological, and sociocultural contexts;

(2) establish short-range and long-range goals and objectives within the Administration for issues of particular concern to women's health within the jurisdiction of the Administration, including, where relevant and appropriate, adequate inclusion of women and analysis of data by sex in Administration protocols and policies;

(3) provide information to women and health care providers on those areas in which differences between men and women exist;

(4) consult with pharmaceutical, biologics, and device manufacturers, health professionals with expertise in women's issues, consumer organizations, and women's health professionals on Administration policy with regard to women;

(5) make annual estimates of funds needed to monitor clinical trials and analysis of data by sex in accordance with needs that are identified; and

(6) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 237a(b)(4) of title 42).

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

(June 25, 1938, ch. 675, §1011, as added Pub. L. 111-148, title III, §3509(g), Mar. 23, 2010, 124 Stat. 536.)

CODIFICATION

Another section 1011 of act June 25, 1938, ch. 675, was enacted by Pub. L. 111-353, title II, §209(a), Jan. 4, 2011, 124 Stat. 3945, and is classified to section 399c of this title.

§ 399c. Improving the training of State, local, territorial, and tribal food safety officials

(a) Training

The Secretary shall set standards and administer training and education programs for the employees of State, local, territorial, and tribal food safety officials relating to the regulatory responsibilities and policies established by this chapter, including programs for—